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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,992	02/19/2003	Raffael Lahav	D01/200	2589

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EXAMINER

OH, SIMON J

ART UNIT PAPER NUMBER

1618

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/018,992

Applicant(s)

LAHAV ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-90 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 40-90 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Papers Received*

Receipt is acknowledged of the applicant's response, request for continued examination, and declaration under 37 C.F.R. § 1.131, all received on 11 April 2005.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 40-90 under 35 U.S.C. 103(a) over Dietrich *et al.* in view of Lundberg *et al.* is hereby withdrawn in view of the declaration under 37 C.F.R. § 1.131 of 11 April 2005.

Claims 40-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Heese *et al.* (U.S. Patent No. 6,623,759) and Bergstrand *et al.* (U.S. Patent No. 5,817,338)

The Heese *et al.* patent discloses benzimidazole derivative compositions comprising a core and a neutralized enteric coating. Specific benzimidazole derivatives that are deemed suitable for the disclosed compositions include omeprazole, lansoprazole, and pantoprazole (See Abstract). Various materials may be used for the enteric coating, including cellulose acetate phthalate and polymethacrylates (See Column 6, Lines 5-20). The enteric coating may contain a plasticizer such as triethyl citrate (See Column 7, Lines 5-9). The enteric coating is preferably

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applied as an aqueous dispersion and neutralized to a pH value of around 5.5 to around 7.0 (See Column 6, Lines 62-67). Suitable bases that may be used to neutralize the enteric coating include sodium hydroxide and potassium hydroxide (See Column 5, Lines 12-20). Tests for the disclosed formulations are described where coatings other than HPMCP are used (See Examples 1 and 2).

Claims 58-60, 76-78 contain limitations reciting a percentage value of the degree of neutralization of an enteric coating material. It is the position of the examiner that such properties are inherent in an enteric coating material of the prior art when the pH of an enteric coating is adjusted to a particular value using known methods. Furthermore, the degree of neutralization as it correlates to the pH of an enteric coating material has already been contemplated by the prior art (See Column 5, Line 1-12). Therefore, these claims are considered to be obvious in view of the prior art.

The Heese *et al.* does not teach the use of a drug core where the active substance is layered over an inert core.

The Bergstrand *et al.* patent teaches a multiple unit dosage form of omeprazole (See Abstract). Each individual unit comprises a drug core and an enteric coating (See Column 4, Lines 2-9). The drug core may be formed from inert cores, with the active ingredient layered over them. The active substance may be mixed with other substances before being layered over the inert core, such as binders. Suitable binders include hydroxypropylmethylcellulose and hydroxylpropylcellulose (See Column 4, Lines 39-67). Suitable enteric coating layer materials include methacrylic acid copolymers, hydroxypropylmethylcellulose acetate succinate, cellulose acetate phthalate, and carboxymethylethylcellulose. Plasticizers may be included in the enteric

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coating layers, such as citric acid esters and phthalic acid esters (See Column 6, Lines 45-64).

Although intermediate layers between the core and the enteric coating layer may be used, the prior art does contemplate embodiments where the enteric coating layer is applied directly over the drug core (See Column 5, Lines 60-67; and Example 8).

It would be obvious to one of ordinary skill in the art to combine the teachings Heese *et al.* and Bergstrand *et al.* into the objects of the instant application. The prior art references both disclose enteric-coated compositions of benzimidazole derivatives, and are therefore considered by the examiner to be analogous art for application against the instant claims. One of ordinary skill in the art would be motivated to combine the disclosures of the prior art references in order to incorporate the neutralized enteric coating layer of Heese *et al.* directly over the drug cores disclosed in Bergstrand *et al.* so that such an embodiment can be made more stable and therefore, more advantageous over what has been previously been disclosed in the prior art. It is the position of the examiner that as the prior art references are analogous art, they can therefore be combined with a reasonable expectation of success in forming stable benzimidazole derivative compositions. Thus, the instantly claimed invention is *prima facie* obvious.

#### ***Response to Arguments***

Applicant's arguments with respect to Claims 40-90 have been considered but are moot in view of the new grounds of rejection. The new grounds of rejection have been made in view of the declaration under 37 C.F.R. § 1.131 of 11 April 2005.

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*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1618

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